



Docket No.: 50179-093

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of :
:
Peter Laurence MOLLOY, et al. :
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Serial No.: 09/914,651 : Group Art Unit: 1636
:
Filed: December 27, 2001 : Examiner: Gerald G. Leffers, Ph.D.
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For: REGULATORY CONSTRUCTS COMPRISING INTRON 3 OF SPECIFIC
MEMBRANE ANTIGEN GENE

RESPONSE TO OFFICE ACTION

Mail Stop Restriction Requirement
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the Office Action of August 11, 2003 in this application. In response to Applicants' remarks, the Restriction Requirement mailed March 26, 2003 has been withdrawn.

Restriction is now required between the inventions identified as those of Groups I-IV:

Group I, claims 54-94: recombinant nucleic acids comprising an enhancer element derived from intron 3 of the PSM gene, and methods of using the recombinant nucleic acids to express genes in a cell

Group II, claims 95-106: methods of treating prostate cancer

Group III, claims 95-106: methods of treating bladder cancer

Group IV, claims 95-106: methods of treating breast cancer

In response to this requirement, Applicants elect the invention of Group I, directed to claims 54-94 for prosecution in this application. This requirement for restriction is respectfully traversed and reconsideration is requested.

Any restriction and election requirements must comply with National Stage requirements as set forth in 37 CFR 1.475 which states that a restriction or election requirement is improper if there is a special technical feature linking various claims in the application. In particular, MPEP 1893.03 states: "A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding technical feature."

The Examiner identifies the special technical feature of Group I to be, "a prostate-derived enhancer element to express any given protein." Alternatively, the Examiner alleges that the "special technical feature for the treatment claims of Groups II-IV is the type of therapeutic nucleic acid that is expressed and the target it attacks in treating a particular kind of cancer." Office Action of August 11, 2003, page 2, last paragraph.

Applicants respectfully disagree and assert that the "special technical feature" linking Groups I-IV is the fact that they all involve usage of a regulatory element derived from intron 3 of the PSM gene.

Applicants direct the Examiner's attention to page 7, line 33 to page 8, line 5 of the specification which indicates that the regulatory constructs of the invention, i.e. those containing regulatory elements derived from intron 3 of the PSM gene, are useful for the expression of proteins in vascular endothelial cells. Moreover, Example 13 on pages 24-25, demonstrates the use of the constructs of the invention to drive expression of GFP in endothelial cells. Given endothelial cells' critical role in nourishing tumors, the constructs can be employed to treat cancers. As preferred embodiments, prostate, bladder, and breast cancers are specifically recited on page 8, line 5. Accordingly, Applicants respectfully submit that all of the claims clearly share at least one common special technical feature.

It is believed that the above represents a complete response to the Official Action and reconsideration is now in order.

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To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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